

The bill was ordered to be engrossed for a third reading and was read the third time.

Mr. SCHUMER. I know of no further debate.

The ACTING PRESIDENT pro tempore. Is there further debate?

If not, the bill having been read the third time, the question is, Shall the bill pass?

The bill (S. 320) was passed, as follows:

S. 320

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE.

This Act may be cited as the “John Lewis NIMHD Research Endowment Revitalization Act of 2021”.

#### SEC. 2. RESEARCH ENDOWMENTS AT BOTH CURRENT AND FORMER CENTERS OF EXCELLENCE.

Paragraph (1) (beginning with “(1) IN GENERAL”) of section 464z-3(h) of the Public Health Service Act (42 U.S.C. 285t(h)) is amended to read as follows:

“(1) IN GENERAL.—The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

“(A) at current or former centers of excellence under section 736; and

“(B) at current or former centers of excellence under section 464z-4.”.

Mr. SCHUMER. I ask that the motion to reconsider be considered made and laid upon the table.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

#### AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO THE SCOPE OF NEW CHEMICAL EXCLUSIVITY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be discharged from further consideration of S. 415 and the Senate proceed to its immediate consideration.

The ACTING PRESIDENT pro tempore. The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (S. 415) to amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

There being no objection, the committee was discharged, and the Senate proceeded to consider the bill.

Mr. SCHUMER. I ask unanimous consent that the bill be considered read a third time and passed and that the motion to reconsider be considered made and laid upon the table.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The bill (S. 415) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 415

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking “active ingredient (including any ester or salt of the active ingredient)” each place it appears and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”;

(B) in subsection (j)(5)(F), by striking “active ingredient (including any ester or salt of the active ingredient)” each place it appears and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”;

(C) in subsection (l)(2)(A)—

(i) by amending clause (i) to read as follows:

“(i) not later than 30 days after the date of approval of such applications—

“(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

“(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and”; and

(ii) in clause (ii), by inserting “or biological product” before the period;

(D) by amending subsection (s) to read as follows:

“(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

“(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

“(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

“(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

“(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.”; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking “active ingredient (including any ester or salt of the active ingredient)” and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”; and

(ii) by striking “same active ingredient” and inserting “same active moiety”;

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking “active ingredient (including any ester or salt of the active ingredient)” each place it appears and inserting “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))”;

(3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)), by amending subparagraph (C) to read as follows:

“(C) is for—

“(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of

title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

“(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.”;

(4) in section 529(a)(4) (21 U.S.C. 360ff(a)(4)), by striking subparagraphs (A) and (B) and inserting the following:

“(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

“(B)(i) is for such a drug—

“(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

“(II) that is the subject of an application submitted under section 505(b)(1); or

“(ii) is for such a biological product—

“(I) that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the Public Health Service Act; and

“(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act.”; and

(5) in section 565A(a)(4) (21 U.S.C. 360bbb-4a(a)(4)), by amending subparagraph (D) to read as follows:

“(D) is for—

“(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

“(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.”.

(b) TECHNICAL CORRECTIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by repealing clause (i); and

(B) in subsection (j)(5)(F), by repealing clause (i); and

(2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C. 355a(c)(1)(A)(i)(II)), by striking “(c)(3)(D)” and inserting “(c)(3)(E)”.

#### RECOGNIZING THE 100TH ANNIVERSARY OF THE HOOSIER GYM AND THE 35TH ANNIVERSARY OF THE RELEASE OF THE FILM “HOOSIERS”

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 102, submitted earlier today.

The ACTING PRESIDENT pro tempore. The clerk will report the resolution by title.

The senior assistant legislative clerk read as follows:

A resolution (S. Res. 102) recognizing the 100th anniversary of The Hoosier Gym and the 35th anniversary of the release of the film “Hoosiers”.

There being no objection, the Senate proceeded to consider the resolution.

Mr. SCHUMER. It was a very good film, I must add.

I ask unanimous consent that the resolution be agreed to; that the preamble be agreed to; and that the motions to reconsider be considered made

and laid upon the table with no intervening action or debate.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The resolution (S. Res. 102) was agreed to.

The preamble was agreed to.

(The resolution, with its preamble, is printed in today's RECORD under "Submitted Resolutions.")

Mr. SCHUMER. Mr. President, I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The senior assistant legislative clerk proceeded to call the roll.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

#### RECOGNITION OF THE MINORITY LEADER

The ACTING PRESIDENT pro tempore. The Republican leader is recognized.

#### NOMINATIONS

Mr. MCCONNELL. Mr. President, yesterday, I voted to advance the nominations of Congresswoman MARCIA FUDGE to be the Secretary of Housing and Urban Development and Judge Merrick Garland to be Attorney General.

These aren't the nominees whom any Republican would have picked for these jobs, but the Nation needs Presidents to be able to stand up a team so long as their nominees are qualified and mainstream. I have voted to confirm people like Secretaries Austin, Blinken, Yellen, Vilsack, and Buttigieg. We certainly disagree on plenty of issues, but I spent 4 years watching many of our Democratic colleagues do everything possible to obstruct and delay President Trump's nominees right from the start.

Now we hear of many of the same Democrats insisting that, as a matter of principle, a new President needs his team and any delay is an outrage. It is funny how some things change. My position has not.

I am voting to confirm Judge Garland because of his long reputation as a straight shooter and a legal expert. His left-of-center perspective has been within the legal mainstream.

For the country's sake, let's hope our incoming Attorney General applies that no-nonsense approach to the serious challenges facing the Department of Justice and our Nation. Let's hope that he controls the bureaucrats and leftist subordinates that the President proposes to place under him, rather than the other way around.

When I spoke to Judge Garland, we discussed his commitment to the ongoing investigation of the events of January 6. Federal law enforcement needs to continue the work of identifying, ar-

resting, and prosecuting those who broke the law in order to disrupt the constitutional business of Congress. He assured me that will remain a priority.

At the same time, it is essential that DOJ treat political violence with equal seriousness no matter which political fringe it may come from. Last summer, riots, vandalism, and even a so-called "autonomous zone" consumed parts of American cities. In some instances, thugs directly attacked Federal property. But amazingly, some local leaders seemed more willing to tolerate the chaos than tolerate the angry tweets that leftwing activists might have sent if they had stepped in to actually do their jobs.

We were fortunate to have Attorney General Barr, who took seriously the Federal Government's role to protect Federal property and enforce Federal law. Judge Garland must be prepared to do the same.

Of course, the riots haven't been the only area where we have seen liberal governance give short shrift to the rule of law. The Obama administration was famous for its willingness to let ideology dictate the enforcement of Federal laws or the lack thereof.

Take the DACA Program, for example. When the Obama administration realized their preferred immigration policies couldn't get through Congress the right way, they stretched prosecutorial discretion and law enforcement discretion to breathtaking unconstitutional extremes. When confirmed, Judge Garland must not back other constitutionally corrosive efforts to effectively repeal laws just by ignoring them.

That brings me to the issue of immigration more broadly. Just a few weeks into the job, the Biden administration and Secretary Mayorkas are flailing and failing on our southern border. The number of unaccompanied migrant children in Border Patrol custody has tripled in just 2 weeks and now dwarfs anything seen during the last 4 years.

Like I mentioned last week, this is not an isolated question of border policy alone. The backdrop behind this entire crisis is the giant push toward amnesty and insecurity that the administration advertised throughout the campaign and every time they step to the podium now. That is what has enticed people to flood in.

Even now, administration staff keeps parroting strange lines like "Now is not the time to come." "Now is not the time to come"? Well, when is the right time to break Federal law? Is there going to be a good time to break into the country illegally, and people need to just be patient and wait for their signal? What on Earth are they talking about?

A lot of blame for this mess rests on Secretary Mayorkas himself. He spent the first weeks of his tenure downplaying and denying the crisis instead of solving it. But, again, the Biden administration's far-left approach to this issue is not limited to

DHS or to the border. Interior enforcement is a key component.

On Secretary Mayorkas' watch, we have seen what the Washington Post calls "a sharp drop" in arrests by Immigration and Customs Enforcement—a collapse of more than 60 percent from just the prior few months—a political choice, in effect, not to enforce the law.

Judge Garland must ensure the Department of Justice takes its duty to uphold the law more seriously.

Mr. President, on a related matter, after we confirm Congresswoman FUDGE and Judge Garland, the Senate will consider two nominees I will not be supporting. They both report straight to the frontlines of the new administration's leftwing war on American energy. They would work to unbalance the balancing act between conservation and the economic comeback we badly need.

To head the Environmental Protection Agency, the President has nominated Michael Regan, a longtime regulator and activist. Mr. Regan has plenty of experience. The problem is what he is poised to do with it. He and the administration are plainly prepared to put that experience behind the same far-left policies that crushed jobs and prosperity in States like Kentucky throughout the Obama administration.

The Clean Power Plan? Back on the table. The absurd waters of the United States rule? Back on the table.

Kentuckians know that when bad policies like those are on the table, it means their jobs, their livelihoods, and their communities are on the menu.

Congresswoman HAALAND, the President's pick to lead the Department of the Interior, was literally an original cosponsor of the Green New Deal. She has vowed to "keep fossil fuels in the ground" and once pledged "to vote against all new fossil fuel infrastructure."

Her record and her views ignore the fact that American energy independence fueled prosperity for the working class and middle class over the last 4 years. Yet in multiple of those years, our carbon emissions actually went down—went down. The supposed choice between a clean environment and domestic energy independence is a false choice. It only exists as a zero-sum tradeoff in the minds of Democrats.

We have every reason to believe that voting for Mr. Regan and Representative HAALAND would be voting to raise gas prices for families who are already struggling, voting to raise fuel and heating bills for seniors on a fixed income, voting to take the tough times we have been going through and making them even tougher.

I will be voting for American families and against both of their nominations.

#### CONCLUSION OF MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Morning business is closed.